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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,849	03/06/2002	Steven T. Boyce	CUT / 02	8604
26875	7590	11/01/2004	EXAMINER	
WOOD, HERRON & EVANS, LLP 2700 CAREW TOWER 441 VINE STREET CINCINNATI, OH 45202			ODLAND, KATHRYN P	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 11/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/091,849

Applicant(s)

BOYCE, STEVEN T.

Examiner

Kathryn Odland

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2004 and 30 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4, 16, 33 and 40-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 16, 33 and 40-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment***

This is a response to the amendments dated June 21, 2004 and August 30, 2004. Claims 1-5, 33 and 40-46 are under consideration.

### ***Specification***

It is noted that on page 9, the application serial number is missing. It is requested that it be provided.

### ***Response to Arguments***

1. Applicant's arguments filed June 21, 2004 regarding claim 33 have been fully considered but they are not persuasive.

Regarding claim 33, applicant argues, "Kushner is non-analogous art, because it is not an apparatus for casting a biologically compatible matrix resulting from freezing of matrix forming fluid." However, the examiner respectfully disagrees both are in the art of molding/casting. Applicant is reminded that that functional language does not hold patentable weight in apparatus claims. Further, the scope of "biologically compatible matrix" is extraordinarily broad. "Biologically" is defined as of, relating to, caused by, or affecting life or living organisms; having to do with biology according to The American Heritage® Dictionary of the English Language, Third Edition copyright © 1992 by Houghton Mifflin Company. The term biologically is extremely broad since it broadly means affecting life. "Compatible" is defined as capable of existing or performing in harmonious, agreeable, or congenial combination with

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another or others: compatible family relationships; capable of orderly, efficient integration and operation with other elements in a system with no modification or conversion required according to The American Heritage® Dictionary of the English Language, Third Edition copyright © 1992 by Houghton Mifflin Company. "Matrix" is defined as a mold or die according to The American Heritage® Dictionary of the English Language, Third Edition copyright © 1992 by Houghton Mifflin Company. Therefore, a biologically compatible matrix is a broad recitation that does not make the Kushner et al. reference non-analogous. Further, freezing is a product-by-process limitation. Moreover, intended use is not given patentable weight. Further, Kushner was relied upon for the teaching of a sixth attachable surface used to form a closed chamber. The claim limitations do not require more than that. The claim is extraordinarily broad. Thus, the previous rejection is reiterated.

2. Applicant's arguments with respect to claims 1 and 40 have been considered but are moot in view of the new ground(s) of rejection.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

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only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 4, and 40-46 are rejected under 35 U.S.C. 102(a and/or e) as being anticipated by Tuurenhout et al. in US Patent No. 6,231,741.

Regarding claims 1, 40, 42 Tuurenhout et al. disclose an apparatus to prepare a biocompatible matrix-forming fluid (where the gel can be considered biocompatible matrix) having a chamber to contain the fluid (gel), where the chamber is defined by a top surface (1) of a heat conductive material (the material will necessarily have some conductivity) and a bottom surface (2) of a heat conductive material (the material will necessarily have some conductivity) and at least one discontinuous gasket (30) having a uniform thickness positioned between the top and bottom where the gasket contains the matrix, as seen in figure 9. Further, there are a plurality of fasteners, such as the components of (8), 43, 42, portions of 31, etc. Specifics of the fasteners are not claimed. Also, the placement of the fasteners is not claimed either.

Regarding claim 4 and 41, Tuurenhout et al. disclose that as applied to claims 1, 40 as well as a chamber that is a bladder. The device can be considered a bladder since the current application specification does not provide a special definition for the term "bladder."

Claims 43-46 are apparatus claims that appear to contain method limitations. Thus, only the structural limitations are given patentable weight. Thus see the

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rejection above for the structural limitations in the corresponding rejections of claims 1, 40 and 42.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tuurenhout et al. in US Patent No. 6,231,741.

Regarding claim 5, Tuurenhout et al. disclose that as applied to claim 1. However, Tuurenhout et al. do not recite a heat conductive material that is metal. However, the current application specification at page 14 recited that the material may be made of any substantially rigid substance such as wood, ceramic, or can be considered an equivalent since the current application specification does not recite the criticality of any particular material.

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8. Claims 1-5, 33 and 40-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyce in US Patent No. 5,976,878 in view of Tuurenhout et al. in US Patent No. 6,231,741.

Boyce discloses the apparatus, as seen in figure 8 with the exception of a discontinuous gasket. On the other hand, Tuurenhout et al. teach a discontinuous gasket (30). Thus it would be obvious to one with ordinary skill in the art to modify the invention of Boyce to include a discontinuous gasket as taught by Tuurenhout et al. for the purpose of enhanced ability to better insert, manage and mold the matrix material.

9. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boyce in US Patent No. 5,976,878 in view of Kushner et al. in US Patent No. 4,954,236.

See the previous rejection and that stated above in the Response to Arguments section.

### ***Conclusion***

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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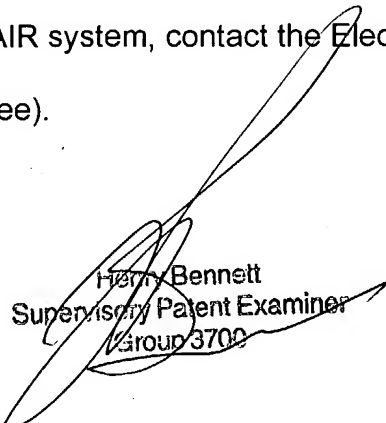
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KO



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